510K Summary K112864 page 1/2

AUG 2 2012

Submitted by:	Chitogen Inc 7255 Ohms Lane Minneapolis, MN 55439 Phone: (952) 835-5707 Fax: (952) 835-5040
Contact Person:	James F. Drake
Date Prepared:	September 28, 2011
Proprietary Name:	*SoftSeal-C*
Common Name:	Topical Hemostasis Pad
Classification:	Unclassified
Classification Name:	Topical Wound Dressing Pad
Product Code:	FRO
Predicate Devices:	Chitogen SoftSeal-*STF* K-090100, (by reference) HemCon Bandage-OTC K-0309046
Device Description:	*SoftSeal-C* pad is a sterile topical pad, packed in a foil pouch, and sterilized with gamma irradiation to a 10^{-6} SAL. The *SoftSeal-C* pad is a non-woven pad composed of chitosan fibers attached to a thin polypropylene backing material. The *SoftSeal-C* is formed as a 1" by 1" square pad 0.4'' thick. The soft, fleece-like pad consists of fine (5 to 20 micrometer) chitosan fibers spun from high molecular weight chitosan. The chitosan fleece is attached to a thin polypropylene backing, which provides dimensional support for fabricating and handling the soft fibers.
Intended Use:	The *SoftSeal-C* pad made by Chitogen Inc. is intended for use in the management of minor topical bleeding wounds such as minor abrasions and minor skin lacerations.

Technological Characteristics:

The Chitogen Inc. *SoftSeal-C* pad is a non-woven pad made of a proprietary formulation of chitosan (poly-D-glucosamine and poly-N-acetylglucosamine). Several biomedical applications of chitosan have been reported. These studies represent research on the safety and use of these materials, published over a period of decades by scientists from around the world. This large body of scientific literature satisfies the requirement that a general recognition of safety is commonly accepted throughout the scientific community. For recent review articles, see for instance; "Hemostatic Agents Derived from Chitin and Chitosan," Hudson, et al, Journal of Macromolecular Science, Part C, Polymer Reviews 45:309-323, 2005, "Chitin and Chitosan: Functional Biopolymers from Marine Crustaceans" Kurita, K., Marine Biotechnology 5:203-226, 2006, "Chitins and Chitosans as Immunoadjuvants and Non-Allergenic Drug Carriers," Muzzarelli, R.A., Marine Drugs 8:292-312, 2010.

This formulation has many advantageous properties in applications as a wound dressing, such as biocompatibility and hemostatic activity.

The technological characteristics of the *SoftSeal-C* pad are the same as the predicate device (*SoftSeal*-STF and HemCon Bandage OTC). The Chitogen *SoftSeal-C* pad works in the same manner as the approved predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 2 2012

Chitogen, Incorporated
% Mr. James Drake
7255 Ohms Lane
Minneapolis, Minnesota 55439

Re: K112864
Trade/Device Name: SoftSeal-C
Regulatory Class: Unclassified
Product Code: FRO
Dated: June 14, 2012
Received: June 21, 2012

Dear Mr. Drake:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K112864

Device Name: SoftSeal-C

Indications for Use:

SoftSeal-C is indicated for use in the management of minor topical bleeding wounds such as minor abrasions and minor skin lacerations.

Prescription Use __ **Over-The-Counter Use _X_**

(Part 21 CFR 801 Subpart D) **AND/OR** **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112864